242 EDITORIALS

Incident analysis

Analysis of clinical incidents: a window on the system not a search for root causes

C A Vincent

It is time to pay more attention to incident analysis

ncident reporting lies at the heart of many initiatives to improve patient safety. The UK National Patient Safety Agency (NPSA)1 has recently launched a national reporting and learning system following substantial piloting and testing across the National Health Service (NHS). In the USA the Agency for Healthcare Research and Quality (AHRQ) made incident reporting the centrepiece of its first patient safety funding programme, investing \$25 million in the first year into research in incident reporting systems.2 The Australian incident monitoring system has amassed a massive database of reports over 15 years.3 New risk management and patient safety programmes—whether local or national—rely on incident reporting to provide data on the nature of safety problems and to provide indications of the causes of those problems and the likely solutions.

Incident reports by themselves, however, tell you comparatively little about causes and prevention, a fact which has long been understood in aviation.4 Reports are often brief and fragmented; they are not easily classified or pigeon holed. Making sense of them requires clinical expertise and a good understanding of the task, the context, and the many factors that may contribute to an adverse outcome. At a local level, review of records and, above all, discussions with those involved can lead to a deeper understanding of the causes of an incident. Surprisingly little attention, however—and even less funding—has been given to the key issue of incident analysis.

PERSPECTIVES ON CLINICAL INCIDENTS

A clinical scenario can be examined from a number of different perspectives, each of which may illuminate one facet of the case. Cases have, from time immemorial, been used to educate and reflect on the nature of disease. They can also be used to illustrate the process of clinical decision making, treatment options and sometimes, particularly

when errors are discussed, the personal impact of incidents and mishaps. Incident analysis, for the purposes of improving the safety of health care, may encompass all of these perspectives but, critically, also includes reflection on the broader healthcare system. This process is usually known by the wholly inappropriate term "root cause analysis".⁵

There are a number of methods of incident investigation and analysis available in health care. In the USA the most familiar is the root cause analysis approach of the Joint Commission, an intensive process with its origins in total quality management approaches to healthcare improvement.⁶ The Veterans Hospital Administration has developed a highly structured system of triage questions which is being disseminated throughout their system.7 In the UK the Clinical Safety Research Unit has developed a "systems analysis" of incidents based on Reason's model and our own framework of contributory factors.89 A revised and updated version is now available.10 11 The NPSA has developed a root cause analysis teaching programme which is an amalgam of elements of all these approaches.

A WINDOW ON THE SYSTEM

We have described our own approach to the analysis of incidents as a systems analysis rather than a root cause analysis. The term "root cause analysis", while widespread, is misleading in a number of respects. To begin with, it implies that there is a single root cause, or at least a small number. Typically, however, the picture that emerges is much more fluid and the notion of a root cause is a gross oversimplification.5 9 Usually there is a chain of events and a wide variety of contributory factors leading up to the eventual incident. A more important and fundamental objection to the term "root cause analysis" relates to the very purpose of the investigation. Surely the purpose is obvious? To find out what happened and what caused it. Certainly, it is necessary to find out what happened

and why in order to explain to the patient, his or her family, and others involved. However, if the purpose is to achieve a safer healthcare system, then it is necessary to go further and reflect on what the incident reveals about the gaps and inadequacies in the healthcare system in which it occurred. The incident acts as a "window" on the system-hence systems analysis. Incident analysis, properly understood, is not a retrospective search for root causes but an attempt to look to the future. In a sense, the particular causes of the incident in question do not matter as they are now in the past. However, the weaknesses of the system revealed are still present and could lead to the next incident.

PROSPECTIVE AND RETROSPECTIVE APPROACHES

Prospective analyses of systems are increasingly being explored in health care on the reasonable argument that it is better to examine safety proactively and to prevent incidents before they happen. Incident analysis is usually seen as retrospective while techniques such as Failure Modes and Effects Analysis (FMEA), which examine a process of care, are seen as prospective. FMEA and related approaches are being trialled in a variety of settings and endorsed by the US Veterans Administration, UK NPSA, and others.12 13 We might think that, as health care becomes safer, these prospective analyses will eventually supplant incident analysis. Leaving aside the fact that health care has rather a long way to go before the supply of incidents dries up, there are a number of reasons for continuing to explore individual incidents as well as examining systems prospectively.

Firstly, there is no sharp division between retrospective and prospective techniques; as argued above, the true purpose of incident analysis is to use the incident as a window onto the systemin essence, looking at current weaknesses and future potential problems. Conversely, so called "prospective analysis" relies extensively on the past experience of those involved. Probabilities and hazards assessed in FMEA are derived almost exclusively from groups of clinicians on the basis of their past experience. Techniques such as FMEA are, in addition, very expensive in terms of time and resources.13 The analysis of single incidents—whether or not they have a bad outcome—can be scaled to the time and resource available, be it 10 minutes or 10 days.14 A single incident—a story—almost always engages a clinical group and can be analysed by an individual risk manager **EDITORIALS** 243

or a whole clinical team. The future probably lies in a judicious application of both forms of techniques, using systems analyses of incidents to generate both enthusiasm and hypotheses as a basis for more resource intensive analyses of whole processes and

A major concern with all the techniques discussed is the lack of formal testing and evaluation. The process of analysing incidents could be considered simply as a method of engaging teams in reflecting on safety; in that case, formal evaluation may not be critical. However, if we believe it could function as a more formal diagnostic technique exposing flaws in healthcare systems, then questions of inter-rater reliability and the validity of the conclusions become important. With vast funds being sunk into the research and development of reporting and tracking of incidents, it is perhaps time to pay more

attention to the ultimately more important-but greatly neglected-issue of incident analysis.

Qual Saf Health Care 2004;13:242-243. doi: 10.1136/qshc.2004.010454

Correspondence to: Professor C A Vincent, Smith & Nephew Foundation Professor of Clinical Safety Research, Department of Surgical Oncology and Technology, Imperial College School of Science, Technology and Medicine, St Mary's Hospital Campus, London W2 1NY, UK; c.vincent@imperial.ac.uk

REFERENCES

- 1 National Patient Safety Agency. www.npsa.nhs.uk (accessed 8 June 2004).
- 2 Agency for Healthcare Research and Quality ww.ahrq.gov, 2004.
- 3 Runciman B, Merry A, McCall Smith A. Improving patients' safety by gathering information. BMJ 2001:**323**:298.
- 4 Cook RI, Woods DD, Miller CA. A tale of two stories: contrasting views of patient safety, US National Patient Safety Foundation, 1998.
- 5 Vincent C. Understanding and responding to adverse events. N Engl J Med 2003;348:1051-6.

- 6 Spath P, ed. Error reduction in health care: a systems approach to improving patient safety. Washington: AHA Press,
- 7 Stalhandske E, Bagian JP, Gosbee J. Department of Veterans Affairs patient safety program. AJIC: Am J Infection Control . 2002:**30**:296–302.
- Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ* 1998;**316**:1154–7.
- Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. BMJ 2000:320:777-81.
- 10 Clinical Safety Research Unit. www.csru.org.uk (accessed 8 June 2004).
- 11 Institute for Healthcare Improvement.
- www.ihi.org (accessed 25 June 2004). **DeRosier J**, Stalhandske E, Bagian JP, *et al.* Using health care failure mode and effect analysis: the VA National Center for Patient Safety's prospective risk analysis system. Jt Comm J Qual Improv 2002;**28**:248–67.
- 13 McNally KM, Page MA, Sunderland B. Failure-mode and effects analysis in improving a drug distribution system. Am J Health System Pharmacy 1997;54:171-7.
- 14 Frankel A, Graydon-Baker E, Neppl C, et al. Patient safety leadership walk rounds. Jt Comm J Qual Improv 2003;29:16-26.

Statistical process control

Using statistical process control to improve the quality of health care

M A Mohammed

To achieve continuous quality improvement "it is not enough to do your best ..."

ontinuous improvement in health care and elsewhere is not a con-which this may be achieved is the subject of much debate. A key aspect of continuous improvement is the measurement, analysis, and interpretation of variation. Consider, for example, the data in table 1 which shows surgeon specific mortality rates after colorectal cancer surgery.1 Ranking the mortality rates or the adjusted hazard ratios, with or without statistical tests, invites the interpretation that some surgeons are better than others. Furthermore, since a hazard ratio of 1 is defined as neutral, surgeons with a hazard ratio above 1 are considered a hazard to their patients. So, by categorising the hazard ratio as either acceptable or unacceptable, the study concludes that "some surgeons perform less than optimal surgery; some are less competent technically than their colleagues..." To improve outcomes the next logical step is to stop the less competent surgeons from operating and transfer their patients to the more competent surgeons. Surprisingly, perhaps, there is another way of analysing these data using statistical process control (SPC) which leads to very different conclusions.

BACKGROUND TO STATISTICAL PROCESS CONTROL (SPC)

In the 1920s Walter A Shewhart, a physicist, was charged with improving

the quality of telephones in Bell Laboratories, USA. His work there won him the accolade of the "father of modern quality control".2 Shewhart developed a theory of variation3 which forms the basis of SPC. His theory is easily illustrated. Consider the first five "QSHC" signatures in fig 1. Two important observations can be made: (1) despite being produced by the same process, they show variation; and (2) the variation is controlled—it lies within certain limits. If nothing is known about the underlying process one would be justified in suggesting that the process appears to be stable. What would traditional approaches to understanding variation tell us about these signatures? The five signatures could be compared to a standard, and some would fall below the standard. A league table could be created, ranking the signatures from best to worst. A statistical test might identify one signature as significantly different from the others. These

 Table 1
 Surgeon specific mortality rates following colorectal cancer surgery

Surgeon	No of cases	No (%) died	Case mix adjusted HR
A	98	16 (16)	1.10
В	66	8 (12)	1.03
C	58	9 (16)	0.87
D	52	7 (13)	1.09
E	52	15 (29)	1.09
F	46	5 (11)	0.86
G	38	3 (8)	0.86
Н	37	11 (30)	1.61
I	36	5 (14)	0.91
J	34	7 (21)	1.05
K	32	4 (13)	0.59
L	21	2 (10)	0.97
M	21	3 (14)	0.79

HR. hazard ratio.